

Actions Taken by FDA Center for Veterinary Medicine

The following corrections or additions to the January 2002 list were published in the Federal Register in October 2002.

Supplemental Approvals

NADA Number: 141-053

This supplemental application provides for the veterinary prescription use of carprofen caplets for the control of postoperative pain associated with soft tissue and orthopedic surgery.

Trade Name: Rimadyl® Caplets
Ingredients: Carprofen
Sponsor: Pfizer, Inc.
Approval Date: July 8, 2002
Status: Prescription only
Route: Oral
Species: Dogs
Drug Form: Tablet (caplet)
Concentration: 25, 75, or 100 milligram caplet
Indications: For the control of postoperative pain associated with soft tissue and orthopedic surgery and for the relief of pain and inflammation associated with osteoarthritis.
Patent Number: 4,264,500 Expiration Date: February 28, 2003
6,013,808 April 15, 2019
Exclusivity: 3 years

21CFR 520.309

NADA Number: 141-111

This supplemental application provides for the veterinary prescription use of carprofen chewable tablets for the control of postoperative pain associated with soft tissue and orthopedic surgery.

Trade Name: Rimadyl® Chewable Tablets
Ingredients: Carprofen
Sponsor: Pfizer, Inc.
Approval Date: August 21, 2002
Status: Prescription only
Route: Oral
Species: Dogs
Drug Form: Tablet
Concentration: 25, 75, or 100 milligram tablet
Indications: For the control of postoperative pain associated with soft tissue and orthopedic surgery and for the relief of pain and inflammation associated with osteoarthritis.
Patent number: 4,264,500 Expiration Date: February 28, 2003
6,013,808 April 15, 2019

21CFR 520.309

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Change of Sponsor

NADA Numbers:	039-356	039-357	042-740	042-837	044-015
	045-455	045-513	049-553	092-237	093-688
	101-079	102-437	104-184	107-085	126-237

From: Cyanamid Agricultural de Puerto Rico, Inc.

To Fort Dodge Animal Health, A Division of American Cyanamid Co.
Drug labeler code: 053501
P.O. Box 1339
Fort Dodge, IA 50501

Suitability Petition Action

Number: 02P-0423/CP1
Sponsor: Highland VetPharma, LLC
Petition: Request permission to file an ANADA for a generic new animal drug ivermectin/pyrantel which differs from the pioneer product, ivermectin/pyrantel (Heartgard[®] Plus), Merial Ltd., NADA 140-971 by the following characteristics: the generic product will consist of a different dosage form (molded chewable tablet) from the pioneer (extruded chewable tablet).

Action: Filed on September 26, 2002.

Number: 02P-0429/CP1
Sponsor: Highland VetPharma, LLC
Petition: Request permission to file an ANADA for a generic new animal drug ivermectin which differs from the pioneer product, ivermectin (Heartgard[®] for Cats), Merial Ltd., NADA 141-078 by the following characteristics: the generic product will consist of a different dosage form (molded chewable tablet) from the pioneer (extruded chewable tablet).

Action: Filed on September 30, 2002.

Number: 01P-0427/CP1
Sponsor: Karen A. Sisson
Petition: Request permission to file an ANADA for a generic new animal drug ivermectin which differs from the pioneer product, Eqvalan[®], Merial Ltd., NADA 134-314 by the following characteristics: The generic product will consist of a different dosage form (liquid) from the pioneer.

Action: Approved on October 21, 2002.

Extension of Patent Expiration

NADA Number: 141-107

Tradename: Bapten[®]
Sponsor: Alaco, Inc.
Patent Number: 4,485,088

Expiration Date: March 26, 2007